K092824

AlphaProTech INCORPORATED

OCT 21 2009

Abbreviated 510(k)
For Alpha Pro Tech, Inc
695 N95 Respirator Mask with Positive Facial Lock and Magic Arch

SECTION 5
510(k) SUMMARY

Submitter:

Alpha Pro Tech, Inc.
236 North 2200 West
Salt Lake City, Utah 84116
Registration Number 1721663

Contact:

David Kitchen
Corporate QA/RA Manager
Telephone: 801.355.5816
Fax: 801-355-2534
E-mail: dkitchen@alphaprotech.com

Trade Name:

Alpha Pro Tech 695 N95 Respirator Mask, Positive Facial Lock with Magic Arch

Model Numbers:

695

Common Name:

Healthcare N95 Particulate Respirator Mask

Predicate Device:

Alpha Pro Tech's 695 N95 Respirator Mask has the same technological characteristics as Aearo Company's Pleats Plus 1050 Respirator Masks in that both are NIOSH approved; both are made of nonwoven meltblown polypropylene; both incorporate a forming nosepiece, both employee a flat pleated style; and both are secured using dual elastic head straps.

Classification:

Device Class – Class II
Product Code – MSH – Surgical N95 Respirator
CFR Section – 21 CFR 878.4040

Device Description:

Alpha Pro Tech's 695 N95 Respirator Masks consists of a polypropylene meltblown filter media sandwiched between non-woven wetlaid outer and inner covers. The mask is secured using two polyester covered non-latex rubber headbands. Fitting around the face is facilitated using a nose wire and an adjustable chin wire made from aluminum. No fiberglass media is used in this product.

Intended Use:

Alpha Pro Tech's 695 N95 Respirator Masks meet the CDC guidelines for TB Exposure Control within healthcare facilities. These devices are intended to be worn by healthcare personnel during surgical procedures to protect both the patient and healthcare personnel from the transfer of

microorganisms, body fluids, and particulate material. Intended use includes use as a procedure mask, isolation mask and/or dental face mask. The 695 mask is a single use, disposable device.

Limitations:

The application of the 695 mask does not eliminate the risk to the wearer of contracting any type of disease or infection. The mask should be changed immediately if contaminated with blood or body fluids.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. David Kitchen
Corporate Quality Assurance/Regulatory Affairs
AlphaProTech, Incorporated
236 North 2200 West
Salt Lake City, Utah 84116

OCT 21 2009

Re: K092824
Trade/Device Name: Alpha Pro Tech 695 N95 Respirator Mask, Positive Facial Lock with Magic Arch
Regulation Number: 21CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: October 1, 2009
Received: October 7, 2009

Dear Mr. Kitchen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Abbreviated 510(k)
For Alpha Pro Tech, Inc
695 N95 Respirator Mask with Positive Facial Lock and Magic Arch

SECTION 4
INDICATION FOR USE STATEMENT

510(k) Number (if known):

Device Name: Alpha Pro Tech 695 N95 Respirator Mask, Positive Facial Lock with Magic Arch

Indications for Use:

Alpha Pro Tech's 695 N95 Respirator Mask meets the CDC guidelines for TB Exposure Control within healthcare facilities. These devices are also intended to be worn by healthcare personnel during surgical procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. It is intended to be a single use, disposable device. This would also include use as a procedure mask, isolation mask and/or dental face mask.

Prescription Use _____ AND/OR Over-The Counter Use ___X___
(Part 21 CFR 801 Subpart-D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092824